

EXHIBIT 3



U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Home Inspections, Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters

Redco Foods, Inc. 2/22/10



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Mr. Douglas N. Farrell, General Manager
Redco Foods, Inc.
One Hansen Island
Little Falls, NY 13365

Re: CFSAN-OC-10-10

Dear Mr. Farrell:

The Food and Drug Administration (FDA) has reviewed the label for your "Salada Naturally Decaffeinated Green Tea" product and your website www.greentea.com. Based on our review, we have concluded that your green tea products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at www.fda.gov.

Unapproved New Drug

Your website, www.greentea.com, promotes your green tea products for conditions that cause them to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. Examples of disease claims that cause your products to be drugs include:

On a web page entitled "About Green Tea":

"A Steaming Cup of Medicine" Article:

- "And today, scientific [sic] are ... finding that green tea can ... inhibit the cancer process at virtually every stage, regulate cholesterol levels ... and ward off viruses, fungi and food-borne bacteria."
- "[I]t also helps inhibit dental plaque formation, lower the risk of type 2 diabetes"

"The Origins of Tea" Article:

- "By this time, tea was prized as a medicine that could cure digestive disorders ..."
- "The tea leaves were also applied externally as a paste to ease the pains of rheumatism."

"Is Green Tea a Brain Food?" Article:

- "[R]ecent studies of the effects of green tea's catechins on animal brains are intriguing:

o "* Less buildup of plaque[.] Finally, mice specially bred to develop Alzheimer's disease developed up to 54% less beta-amyloid buildup in their brains when they were given daily injections of the green tea catechin EGCG.... Beta-amyloid plaques are believed to be a major cause of the brain cell death and tissue loss seen in Alzheimer's disease."

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The therapeutic claims on your website establish that your green tea products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your green tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201 (p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your green tea products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your green tea products are misbranded under section 502(f)(1) of the Act in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Unauthorized Health Claims

Your green tea products are further misbranded under section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because its labeling bears unauthorized health claims. Your website, www.greentea.com, was reviewed and was found to contain a number of unauthorized health claims, including:

"Green Tea and the FDA: Who's Right?" Article:

- "[O]ver the past 25 years, countless studies showing the positive effect of green tea on several important risk factors for cardiovascular disease have been published in scientific journals."
- "[M]ost studies have shown that green tea reduces certain CVD risk factors with a daily intake of 4-5 cups"

The above claims are unauthorized health claims because there is no health claim authorized by regulation or the Act that provides for health claims that characterize the relationship between green tea and cardiovascular disease.

Unauthorized Nutrient Content Claims

Under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The principal display panel of the product label includes the statement "Fortified with Purple Antioxidants [/] Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins ...". In the context of the label, the term "antioxidants" refers, in part, to grapeskins, rooibos (red tea), and anthocyanins. The term "fortified" is defined by regulation and may be used to describe the level of certain substances for which an RDI or Daily Reference Value (DRV) has been established [21 CFR 101.54(e)]. However, there are no RDIs or DRVs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins" is unauthorized and misbrands your product under section 403(r)(1)(A) of the Act.

In addition, nutrient content claims using the term "antioxidant" may only be made for nutrients for which a Reference Daily Intake (RDI) has been established [21 CFR 101.54(g)(1)]. As noted above, there are no RDIs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Purple Antioxidants ... Grapeskins, Rooibos (Red Tea), Anthocyanins" is an unauthorized nutrient content claim that causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The label for this product also bears the unauthorized nutrient content claim "One of the antioxidants known as EGCG (Epigallocatechin gallate) is abundantly found in green tea leaves." This claim is a nutrient content claim because "abundantly found" characterizes the level of EGCG in your product [see section 403(r)(1) of the Act (21 U.S.C. § 343(r)(1)) and 21 CFR 101.13(b)]. Even if we determined that the term "abundantly found" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). This claim does not comply with 21 CFR 101.54(g)(1) because no RDI has been established for EGCG. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Kathleen M. Lewis, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint

Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

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Roberta F. Wagner
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA New York District

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